

PROACTIV REPAIRING TREATMENT- benzoyl peroxide lotion

Guthy-Renker LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

proactiv®

SOLUTION

Repairing Treatment

Drug Facts

Active ingredient

Benzoyl Peroxide 2.5%

Purpose

Acne treatment

Use

for the management of acne

Warnings

For external use only

Do not use this medication if you

- have very sensitive skin.
- are sensitive to benzoyl peroxide.

Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product.

When using this product

- avoid unnecessary sun exposure and use a sunscreen.
- avoid contact with the eyes, lips and mouth.
- skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if irritation becomes severe.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- cleanse the skin thoroughly before applying this product.
- cover the entire affected area with a thin layer 1 to 3 times daily.
- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- **if going outside, use a sunscreen.**

Other information

- sensitivity test: apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated.
- avoid contact with hair and dyed fabrics, which may be bleached by this product.

Inactive ingredients

water (aqua), ethoxydiglycol, cyclotetrasiloxane, propylene glycol, cetearyl alcohol, dimethicone, glyceryl stearate, PEG-100 stearate, cyclopentasiloxane, panthenol, allantoin, xanthan gum, cetareth-20, carbomer, triethanolamine, diazolidinyl urea, methylparaben, propylparaben, fragrance (parfum)

Dist. by Guthy-Renker®

PO Box 14383

Palm Desert, CA 92255-4383

proactiv.com

PRINCIPAL DISPLAY PANEL - 89 mL Carton

Rodan & Fields

proactiv®

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Treatment

3

benzoyl peroxide acne treatment

3 FL. OZ. 89 mL



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benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	2.5 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-044-10	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:11410-044-20	60 mL in 1 BOTTLE, PLASTIC		
3	NDC:11410-044-35	90 mL in 1 BOTTLE, PLASTIC		
4	NDC:11410-044-32	90 mL in 1 BOTTLE, PLASTIC		
5	NDC:11410-044-40	120 mL in 1 BOTTLE, PLASTIC		

6	NDC:11410-044-89	89 mL in 1 BOTTLE, PLASTIC		
7	NDC:11410-044-23	1 in 1 BOX		
7	NDC:11410-044-20	60 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part333D	03/30/2009	

Labeler - Guthy-Renker LLC (608315453)

Revised: 8/2010

Guthy-Renker LLC